

From: Jamie Newell
To: Brad Nelson
Sent: 5/19/2011 1:13:38 PM
Subject: DEA_MOA_Webinar_Walmart 030411.ppt

PLAINTIFFS TRIAL
EXHIBIT

P-07846_00001

Produced in Native Format



Good Afternoon,

This is Susanne Hiland, Sr. Director of Regulatory Affairs. Thank you for joining me this afternoon. Joining me this afternoon are

Paul Beahm, Sr. Vice President for Health and Wellness

And Andy Gottman, Associate General Counsel, Health and Wellness Legal

As you can see from the title of this presentation we will be discussing a very important issue related to the Drug Enforcement Administration or (DEA).

This issue deals with an agreement between the Company and the DEA.

Please pay careful attention to the information provided.

Overview

Market Directors and above

- Introduction
- Background
- Communication and training plan outline
- Expectations

2

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This presentation is divided into two distinct sections,
Part 1 is directed at our field supervisors and home office personnel.

Part 1 we will cover.....

Close Part 1 with a discussion of the expectations for you as a result of
this Agreement.

Overview

Recorded presentation for pharmacists

- Introduction
- Background
- Obligations
- Policy updates and expectations
- Training
- Consequences of non-compliance
- Closing

3

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At the conclusion of Part 1

We will transition to Part 2 of the presentation which is being recorded for our pharmacists.

For the pharmacists we will cover...

Introduction

Your attention is needed for the full presentation.

Background – Order to Show Cause

- In November 2009, the DEA began an enforcement action against Wal-Mart Stores, Inc. based on several allegations:
 1. Improper dispensing of controlled substances based on prescriptions written by out-of-state prescribers;
 2. Improper dispensing of controlled substances based on prescriptions not issued for a legitimate medical purpose;
 3. Improper dispensing of controlled substances to patients whom the pharmacists knew or should have known were diverting controlled substances;
 4. Use of expired, suspended and/or invalid DEA numbers to fill prescriptions; and
 5. Early refill of controlled substances.

Background - Administrative Memorandum of Agreement (MOA)

- Over the course of 15 months, Walmart and the DEA extensively negotiated an Administrative Memorandum of Agreement (MOA).
- The MOA applies to all Wal-Mart Stores, Inc. pharmacies, including Sam's Club and Puerto Rico.
- The MOA applies only to actions occurring after the effective date of the Agreement, which is to be determined.
- The term of the Agreement is four (4) years.
- Walmart will not pay any monetary fines or sanctions.

Administrative Memorandum of Agreement (MOA)

- Obligations
 - a. Maintain a compliance program
 - Must be designed to detect and prevent diversion of CS.
 - Shall include procedures to identify signs of diversion, including:
 - » Doctor-shopping;
 - » Early refills;
 - » Altered and forged prescriptions;
 - » Prescriber licensure limitations by jurisdiction;
 - » Prescriptions written for an illegitimate purpose; and
 - » Scope of practice.
 - Requires reporting of losses/theft.
 - Requires routine and periodic training of all associates.

6

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Now let's discuss our obligations under the agreement.

I am going to cover the information as an overview.

Additional data will be provided in Part 2 of the presentation.

Administrative Memorandum of Agreement (MOA)

- Obligations
 - b. Notification within 7 business days of refusal to fill a controlled substance prescription based on pharmacist's affirmative conclusion that prescription is forged, altered, or issued for other than a legitimate purpose.
 - c. Compliance with state laws that require ID check for dispensing of controlled substances.
 - d. Compliance with state laws related to out-of-state prescribing.
 - Includes requirement to establish a valid prescriber-patient relationship prior to dispensing.
 - e. Verification of prescriber DEA numbers to ensure that they are valid and active.
 - f. Make certain records available to DEA agents, task force officers and/or investigators upon request.

Administrative Memorandum of Agreement – Terms & Conditions

- Obligations
 - g. Submission of valid information to state Prescription Monitoring Programs (see e. above).
 - h. Allow pharmacists to access PMP information
 - i. Block early refill of controlled substances.
 - Records of overrides of early refill warnings must be made available to law enforcement upon request.
 - j. Install security cameras that capture images of all transactions, including at drive thrus.
 - Video must be maintained for no less than 30 days and made available to law enforcement upon request.
 - k. Report any initiation of legal proceedings regarding dispensing of controlled substances to DEA within 30 days of initiation of the investigation (if not previously reported).

Updated and new policies

- Updated policies
 - POM 1311 – Valid Prescriber/Patient Relationship
 - POM 1315 – Monthly CII Audits
 - POM 1316 – Prescription Monitoring Programs
 - POM 1703 – Forged or Altered Prescriptions
- New policies
 - POM 1313 – Proper Identification (controlled substances and PSE)
 - POM 1317 – Out-of-State Prescribers
 - POM 1318 – Early Refills
 - POM 1319 – Pharmacy Added Prescriber ID

9

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There are eight policies that are impacted by this settlement.

Communication timeline

Date	Activity
Thursday, March 17 th	Letters mailed to pharmacists
Friday, March 18 th	New and updated policies included in Leadership Weekly
Monday, March 21 st	New and updated policies and recorded webinar posted to the WIRE
Wednesday, March 30 th	Last day for pharmacists to view webinar
Friday, March 18 th	Information on controlled substance training modules included in Leadership Weekly
Monday, March 21 st	Information on controlled substance training modules posted to WIRE
Tuesday, March 22 nd	Controlled substance training modules become available on GLMS
Friday, June 24 th	Completion due date for all controlled substance training modules

This timeline is dependent on the DEA's signature on the agreement.

Controlled substance training module schedule

Module	Topic	Seat time	Due date
1	Controlled substance security	~ 25 minutes	4/15/11
2	Dispensing procedures	~ 20 minutes	4/29/11
3	Prescriber/Patient relationship	~ 25 minutes	5/13/11
4	Fraudulent prescriptions and unusual patient behavior	~ 25 minutes	5/27/11
5	Filling and checking (including check out procedures)	~ 25 minutes	6/10/11
6	Audits, reporting and troubleshooting	~ 25 minutes	6/24/11

Sales Associates
will take
Modules 1, 4 and 5
Total time ~ 70 min.

Technicians
will take
Modules 1-5
Total time ~ 2 hrs.

Pharmacists &
Interns will take all
6 Modules
Total time ~ 2.5 hrs.

All modules are currently scheduled to drop into the new GLMS on March 22nd.

Other

- Systems
 - Connexus enhancements will roll out throughout the year to further enhance requirements of the MOA
- Monitoring
 - Compliance monitoring will be on-going
 - CORT questions will focus on compliance with the MOA
- Credentialing
 - Enhanced background and professional credential checks
 - Random drug testing will begin where allowed by law

12

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Additional programs & updates will be introduced in coming months.

Before we move on the exceptions, I want to address an issue that we discussed on our last webinar regarding prescriber ID.

Systems review - input

Input [1 of 1] **New Rx** **Critical**

Shortcuts
 Rx
 Drop-Off
 Input (111/0)
 4 Point Check (14/0)
 Troubleshoot (524/14)
 Visual Verify (42/0)
 Fill (1/3)
 Counseling (3/0)
 Fax (0,0=1)
 Urgent Messages (0)

Patient
 Name: TEST, TEST
 Address: 1111 N. 1ST
 Birth Date: 01/01/1970
 Comment:
 Carrier:
 Plan:
 Rx Written: 02/08/2011
 Expires: 08/09/2011
 On Hold
 Comment: Rx Notes on File

Product/Item
 Prescribed Product: VICODIN ES 7.5-750 TAB
 Smallest Pack Size: 100
 Dispensed: HYDROCO/APAP 7.5-750TAB
 Pack Size: 750
 NDC: 63739-0131-03
 Mfg: SKY PHARMA
 Rating: AA
 Qty: 60
 Disp Qty: 60
 Days: 5
 Sig: PQ4H-PRN/PA
 Expanded Sig: TAKE TWO TABLETS BY MOUTH EVERY 4 TO 6 HOURS AS NEEDED FOR PAIN
 Refills: 2
 DAW: 0-May Substitute
 Language: ENG

Scanner Unavailable
 BarCode Number: 2244

Prescriber
 Name: TEST DR, TEST TESTING
 Address: ABC
 DEA: BA9427370
 Phone: (479)123-4567

No of Rx's: 1
 Add Rx
 Show Order
 Send to Trouble
 Cancel

13 Prescriber Identification - DEA Number



During that webinar I told you that the inputting technician must ensure that the prescriber's address must be selected from the drop down menu available at the bottom of the input screen, indicated here by the green box.

There is a known issue with the prescriber's address reverting to the 'primary' address in the system. We are working on a correction to this issue.

That being said, it remains important that the address selected at input is accurate. This attention to detail must be made a habit for the inputting technician, so this direction has not changed. And of course, the DEA number must be accurate as well.

Expectations

1. Understand that there is **no tolerance** for non-compliance
2. Read and understand the policies
3. Complete the training modules
4. Follow up to ensure pharmacy staff members are completing the required tasks, which include:
 - a. Webinar
 - b. Policies
 - c. Training modules
5. Monitor for understanding and compliance
6. Report all instances of non-compliance

14

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Market Directors, your #1 expectation is to understand that there will be no tolerance for non-compliance.

We are signing a binding agreement with a federal agency.

Before we transition to the pharmacists presentation, I'm going to turn this over to Paul Beahm for a few words.

Paul:_____



We are now going to pause briefly to transition to Part 2 of the presentation that is being recorded for our pharmacists.



Welcome!

Thank you for taking the time to view this presentation that will provide you with important information regarding an upcoming agreement between Wal-Mart Stores, Inc. and the Drug Enforcement Administration (DEA). Over the next hour we will be discussing details of the agreement and what it means to you as a practicing pharmacist. Please pay close attention to the important information that will be provided.

My name is Susanne Hiland and I am Senior Director for Health and Wellness Regulatory Affairs supporting all of our Wal-Mart Stores, Inc. pharmacies which includes Walmart, Sam's Club and Puerto Rico.

Speaking to you today will be Paul Beahm, Senior Vice President for Health and Wellness and

Andy Gottman, Associate General Counsel, Health and Wellness Legal.

Overview

- Introductions
- Background
- Obligations
- Policy updates and expectations
- Training
- Consequences of non-compliance
- Closing

17

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During this presentation we will over the following information.

Background – Order to Show Cause

- In November 2009, the DEA began an enforcement action against Wal-Mart Stores, Inc. based on several allegations:
 1. Improper dispensing of controlled substances based on prescriptions written by out-of-state prescribers;
 2. Improper dispensing of controlled substances based on prescriptions not issued for a legitimate medical purpose;
 3. Improper dispensing of controlled substances to patients whom the pharmacists knew or should have known were diverting controlled substances;
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- Over the course of 15 months, Walmart and the DEA extensively negotiated an Administrative Memorandum of Agreement (MOA).
- The MOA applies to all Wal-Mart Stores, Inc. pharmacies, including Sam's Club and Puerto Rico.
- The MOA applies only to actions occurring after the effective date of the Agreement, which is to be determined.
- The term of the Agreement is four (4) years.
- Walmart will not pay any monetary fines or sanctions.

19

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At the time of this taping we have not yet have the fully executed agreement.

Obligations, policy changes and expectations

Obligations

1. Ensure valid and accurate use of the prescriber's DEA number
(includes submission of data to state monitoring programs)
2. Ensure controlled substance prescription is valid and issued for a valid medical purpose
 - a) Monitor for valid prescriber-patient relationship, including out-of-state prescribers
 - b) Monitor for forged or altered prescriptions
 - c) Report all cases when the pharmacist determines that the prescription or relationship are not valid and therefore does not fill the prescription
3. Comply with state laws requiring ID check
4. Block early refill of controlled substance prescriptions
5. Other obligations

21

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In General – the obligations under the Agreement are as follows.



We will take a detailed look at each of these obligations.

Obligation #1
Ensure valid and accurate use of the prescriber's DEA number
(including accurate submission of data to state monitoring programs)

Overview:

- Connexus prescriber database updated monthly by vendor
- RelayHealth prescriber validation tool available on WIRE
- Pharmacists are responsible for accuracy of the selected prescriber
- 4 point check pharmacist must ensure the DEA number selected matches the DEA number on the hardcopy prescription

22 | Health and Wellness



The first Obligation under the agreement requires our pharmacists to ensure a valid and accurate use of prescriber's DEA number.

Note that this obligation lists that the DEA number must be both VALID and ACCURATE.

We are going to discuss each of these requirements at length.

It is important to not how the prescriber information is handled in Connexus.

Pharmacists must ensure that the prescriber selected at input is correct – the Connexus database must be the first choice when selecting a prescriber. Only after a diligent search of the database should a prescriber be added by the pharmacist.

Prescribers added at pharmacy level should be an exception.

Additional enhancements to the Connexus prescriber database functions are scheduled for the next several months.

Regardless of who selects or inputs the prescriber, the pharmacist who fills the prescription is ultimately responsible, and will be held responsible, for ensuring that the DEA number input is valid and attached to the right prescriber.

Obligation #1

Ensure valid and accurate use of the prescriber's DEA number
(including accurate submission of data to state monitoring programs)

Drug Enforcement Administration (DEA) registration number

- Indicates authorization to prescribe controlled substances
- Never issued without the practitioner having a valid state license
- Medical residents do not have their own DEA numbers
- Residents may use a facility DEA number with an appropriate suffix – a 'special internal code'
- It is never appropriate to use another practitioner's or a dummy DEA number – in fact, it is a violation of state and federal law and Walmart policy, and will result in discipline, up to and including termination.

I want to take a few minutes to remind you of the proper use of a prescriber's DEA number.

Obligation #1

Ensure valid and accurate use of the prescriber's DEA number
(including accurate submission of data to state monitoring programs)

Controlled substance prescription requirements

- From the Code of Federal Regulation
- A valid controlled substance prescription must include the following:
 - » Date issued
 - » Patient's full name and address
 - » Practitioner's full name, address and **DEA number**
 - » Drug name, strength and dosage form
 - » Quantity prescribed
 - » Directions for use
 - » Refills (if authorized)
 - » Manual signature of the prescriber

24

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In order to ensure that the prescriber is accurate, the DEA number must be written on the face of all controlled substance prescriptions. This is a requirement of federal law.

This includes verbal orders and any time a pharmacist takes a verbal order for a controlled substance, they must ask for the DEA number of the prescriber.

Understand that this is a requirement of our obligation that the DEA number is both VALID and ACCURATE.

Obligation #1

Ensure valid and accurate use of the prescriber's DEA number
(including accurate submission of date to state monitoring programs)

Controlled substance prescription requirements

- A valid DEA number must be provided by the prescriber
- DEA number must appear on the face of the hard copy prescription, including **all** oral prescriptions
- The DEA number associated with the prescriber must be accurately recorded in the prescription record in Connexus

i.e.) The DEA number on the hard copy **must** match the prescriber chosen in Connexus

25

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Walmart
Save money. Live better.



Pharmacists must obtain the DEA number from the prescriber or prescriber's agent when a controlled substance prescription is phoned in.

To be clear, the DEA number must be on the face of the prescription when it is imaged into Connexus.

Obligation #1

Ensure valid and accurate use of the prescriber's DEA number
(including accurate submission of data to state monitoring programs)

Accurate submission of prescriber information

- Prescriber profiles are downloaded from a vendor-purchased file monthly
- Lag time between file downloads may mean a prescriber is not in the database
- The database does not include facility information, so Residents working in teaching facilities will never be included
- For these reasons, pharmacists may at times need to add prescribers, but they should only do so after checking the HOST file in Connexus
- New prescriber information added at pharmacy level expires after 45 days

26

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In order to meet this obligation, all pharmacy associates must understand how Connexus handles DEA numbers.

It is important that our pharmacists and technicians understand how to find a prescriber in the HOST system.

It is critically important that prescriber information added at pharmacy level is accurate.

The Connexus database must be the first choice when selecting a prescriber. Prescribers added at pharmacy level should be an exception.

Only after diligent search of the database should a prescriber be added by the pharmacist.

Additional enhancements to the Connexus prescriber database functions are scheduled for the next several months.

Regardless of who selects or inputs the prescriber, the pharmacist who checks the prescription is ultimately responsible, and will be held responsible, for ensuring that the DEA number input is valid and attached to the right prescriber.

Systems review - input

The inputting technician can search the prescriber file by either entering the prescriber's name or by searching the DEA number. Shown here in the red box.

By clicking on the search button, the ... button, Connexus will look for the prescriber, or take you to another screen for a more detailed search.

Technicians should also ensure that the address selected on the input screen, reflects the prescriber's address on the hardcopy prescription. Shown here in the green box

Systems review – prescriber look-up

Search
Prescriber

Name	DEA #	Clinic	Address	Phone	Office
TEST1,TEST1			TEST1 TEST1, AK 12345	1(231)234-1234	
TEST1,TEST2			100 ABC DR BENTONVILLE, AR 85260	(860)752-0836	
TEST100,TEST100 TEST100		TEST100	TEST100 TEST100, TX 12345	(888)886-7890	
TEST100,TEST100 TEST100		TEST100	TEST100 TEST100, TX 12345	(888)886-7890	
TEST1307,TEST TWFAST			WTWTS TWWVY, TN 12345	(123)456-7890	
TEST2,TEST2 TEST2			TEST2 TESTT2, TX 12345	1(231)234-1234	
TEST3,TEST3 TEST3			TEST3 TEST3, AK 12345	1(231)234-1234	
TESTCA PRESCRIBER.BY DIV			A A, CA 12345	(112)332-2234	

82 record(s) found.

28
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To search the local pharmacy's files, enter the prescriber's name, or DEA number where indicated then hit 'Search Now'.

'Search Now' searches the individual pharmacy's local prescriber file.

If the correct prescriber is returned but there is no DEA number available, call the Contact Center for assistance. Associates at the Contact Center can update the prescriber file after validating the DEA number.

If the correct prescriber is not found the next thing to do is search the Host by clicking on the 'Host Look Up' button (outlined in red).

Systems review – prescriber look-up

Search

Prescriber

Name

Clinic Name


Phone

DEA #

State Lic #

Search Now

New Search



Name	DEA #	Address	Phone	



0 record(s) found.

Host Look Up

New...

Close

29 Health and Wellness

Walmart  Suncoast 

If the correct prescriber is not found by searching the HOST, only then can the prescriber be added.

Only after choosing “Host Look Up” and having no records returned, should a new prescriber be added.

Systems review – adding a prescriber

Prescriber Maintenance

Name Information

Last

First

Middle

☐ Hospital DEA used by Doctor in Residency program

Primary Clinic Address/Phone

Street

City State Zip

Phone () - Country

Office () - Fax ☐ Auto Fax

Nurse

Clinic Name

Prescriber Licenses and Identification

DEA Medicare HIN

NPI HCIdca Fed Tax

UPIN Champus SSID

30 Health and Wellness Walmart Suncoast

Do not add a DEA number if the prescription is not for a controlled substance.

Systems review – 4 point

4 Point Check [1 of 1] Rx 4534279 New Rx Fill 9967880 Tote -- Critical

Order Comment: _____ Rx Comment: _____

Rx #: 4534279 **NO ALLERGY INFORMATION ON FILE**

Scanner Unavailable

Barcode Number: 2244

No of Rx's: 1 Add Rx MAX

Patient Information:
 Name: TEST, TEST
 BirthDate: 1/1/1970 Phone: (555)555-5555
 Comment: _____

Product / Item / Refills:
 Prescribed: VICODIN ES 7.5-750 TAB
 Strength: 7.5-750
 Dispensed: HYDROCO/APAP 7.5-750TAB
 Pres Qty: 60
 Disp Qty: 60
 Days Supply: 5
 Refills: 2 Therapeutic Equivalency: AA

SIG: TAKE TWO TABLETS BY MOUTH EVERY 4 TO 6 HOURS AS NEEDED FOR PAIN

DAW: 0=May Substitute

Prescriber:
 Name: TEST DR, TEST TESTING
 DEA: BA9427370 Phone: (479)123-4567

Return To Tech Show Order Illegible Image Accept Cancel

31 Health and Wellness Walmart Sunys

At the 4 point check screen, pharmacists can reroute any input inaccuracy, including the prescriber or the prescriber's DEA number.

Pharmacists should be verifying that the correct DEA number was used for every controlled substance prescription.



Compare the DEA number on the hard copy to the DEA number appearing for the prescriber in the system.

Obligation #1
Ensure valid and accurate use of the prescriber's DEA number
(including **accurate submission of data to state monitoring programs**)

State prescription drug monitoring programs (PMP)

- POM 1316: Prescription Drug Monitoring Programs
- The basic requirement to ensure that prescriptions are filled accurately applies to every pharmacist in every state
- State and federal law requires that prescription records accurately reflect the hard copy prescription
- This is a universal obligation
- Pharmacists are individually responsible for accuracy

32 | Health and Wellness



Related to the obligation to ensure that the prescribers DEA # is being used accurately is the need to submit accurate information to State Prescription Monitoring Programs.

We will talk about prescription monitoring programs in more detail a little later in the presentation.

Regardless of whether your state has an active prescription monitoring program, there is a universal obligation to make sure that information is accurately entered when filling prescriptions.

Obligation #2

Ensure controlled substance prescription is valid and issued for a valid medical purpose

Valid practitioner-patient relationship

- POM 1311 Practitioner-Patient Relationship update
 - Includes additional indications that a valid relationship may not exist
- Includes a requirement to report information to Regulatory Affairs if a prescription is refused by the pharmacist
 - Forged, altered or fraudulent
 - Valid relationship not established
 - Exercise of professional judgment
- New POM 1317 Out-of-State Prescribers

33

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Now we will move to Obligation #2

The issue behind this obligation relates to internet prescribing but also encompasses the issue of invalid prescriber-patient relationship which everyone will recognize as the problem with prescription or pill mills.

POM 1311 Prescriber-Patient Relationship has been updated

Includes additional indications that a valid relationship may not exist

Includes requirement and process for reporting information to Regulatory Affairs if a prescription is refused

New POM 1317 Out-of-State Prescribers

Outlines state specific restrictions for filling controlled substance prescriptions from out-of-state prescribers

Read and understand the new policy

Obligation #2

Ensure controlled substance prescription is valid and issued for a valid medical purpose

Valid practitioner-patient relationship – required reporting

- Requires pharmacists to document and report any controlled substance prescription not filled when:
 - » The prescription is thought or known to be fraudulent as outlined in POM 1703
 - » The prescriber-patient relationship is suspected or determined not to be valid as outlined in POM 1311
- Pharmacists will provide documentation to Regulatory Affairs
- Regulatory Affairs will notify DEA
- This reporting requirement is absolute; failure to comply will result in discipline, up to and including termination.

34

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Let's talk in more detail about this obligation and the reporting that is required.

Again, this obligation relates to the DEA's focus on fraudulent prescriptions and those not issued for a valid medical purpose.

Starting with fraudulent prescriptions.

POM 1703 provides guidance on the expectations for follow up and validation of a controlled substance prescription that you as a pharmacist believe to be forged or altered.

It is important that you read and fully understand this policy.

Provided with the policy are several 'frequently asked questions'. These breakdown various scenarios and issues that are commonly encountered when handling forged or altered prescriptions.

Note that the change on POM 1703 requires reporting of these prescriptions to Regulatory Affairs.

POM 1311 Prescriber-Patient Relationship has also been updated.

Includes additional indications that a valid relationship may not exist

Includes requirement and process for reporting information to Regulatory Affairs if a prescription is refused.

Obligation #3

Comply with state laws requiring ID check

- New POM 1313 - Proper Identification
- Outlines state specific requirements related to checking and recording identification before dispensing controlled substances
- Provides best practices, applicable in all states where there is no specific requirement, for checking identification before dispensing controlled substances, when the patient is new or unknown to staff.
- Paper logs for recording prescription pick up are not allowed

35

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Obligation#3

Obligation #4
Block early refill of controlled substance prescriptions

Early refills of controlled substance

- New POM 1318 Early Refill of Controlled Substances
- Connexus blocks controlled substance refills requested more than 3 days early
- Pharmacists must evaluate each request for an early refill
- Any decision to override must be documented with valid reason
- Records of overrides of early refill warnings will be made available to law enforcement, including the DEA, upon request

36 | Health and Wellness

Obligation #4 (cover the slide)

As a review, the first four obligations in general require:

1. Accurate and valid use of the prescriber's DEA #
2. Ensuring that controlled substance prescriptions were issued for a valid medical purpose, including the existence of a valid prescriber-patient relationship.
3. That we comply with state laws that require an ID check when dispensing controlled substances.
4. A block of early refill of controlled substances.

Now we're going to talk about some additional obligations, the first of which relates back to prescription monitoring programs.

Other obligations

Allow pharmacists to access PMP programs



Access to state prescription monitoring programs (PMP)

- POM 1316 provides links and usage guidelines
- Pharmacists have access to PMP websites in every state that has an active program
- Enrollment is required by each pharmacist that wishes to use the website

Other obligations
Make certain records available to law enforcement, including the DEA

- POM 1304 Pharmacy Inspections
 - » Cooperate with lawful requests for records
- POM 1703 Forged or Altered Prescriptions
 - » Provides guidance on law enforcement requests related to fraudulent prescriptions
 - » Forged or altered prescriptions are not valid and therefore are not subject to HIPAA privacy restrictions
- Report legal proceedings regarding controlled substances to DEA
 - » Home Office obligation

38 | Health and Wellness



•There are a few policies that discuss record requests from law enforcement, including the DEA.

•POM 1304 is titled Pharmacy Inspections and addresses how to handle visits from any Regulatory Agency.

•It is important to understand that you should be professional and courteous when an agency, including law enforcement requests records. You should always cooperate with lawful requests for records.

•If you are unsure of whether the request is lawful, there are many resources available to assist you. These include your Market Manager, Regulatory Affairs, Asset Protection and even the Legal department.

•POM 1703 is often misunderstood. Prescriptions that are known to be forged or altered are not valid, and therefore do not require HIPAA privacy protection.

•Do not fill a known or suspected forged prescription – this is a violation of federal law.

Resources include: Market Director, Regulatory Affairs, Asset

Protection, Legal Department

Other obligations

Install security cameras to capture images of all transactions

- Asset Protection manages cameras and recordings
- Footage must be retained for 30 days and provided to law enforcement upon request
- Any law enforcement requests for video footage should be referred to Asset Protection

Policy reference list

- Updated policies
 - POM 1311 – Valid Prescriber/Patient Relationship
 - POM 1315 – Monthly CII Audits
 - POM 1316 – Prescription Monitoring Programs
 - POM 1703 – Forged or Altered Prescriptions
- New policies
 - POM 1313 – Proper Identification
 - POM 1317 – Out-of-State Prescribers
 - POM 1318 – Early Refills
 - POM 1319 – Prescriber Identification

40

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Here is a recap of the eight policies that are impacted by this Agreement. These policies can be found on the WIRE.

There are additional policies related to controlled substances that are good reference for you as well.

Policy reference list

- Additional policy resources
 - POM 807 – Receiving prescription orders
 - POM 901 – Asset Protection overview
 - POM 902 – Prescription area security
 - POM 903 – Filling Schedule II prescriptions
 - POM 911 – Diversion SOP
 - POM 913 – Post-diversion drug testing
 - POM 1304 – Pharmacy inspections

41

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Here is a recap of the eight policies that are impacted by this settlement. These policies can be found on the WIRE.

There are additional policies related to controlled substances that are good reference for you as well.

Training modules

Controlled substance training module schedule

Module	Topic	Seat time	Due date
1	Controlled substance security	~ 25 minutes	4/15/11
2	Dispensing procedures	~ 20 minutes	4/29/11
3	Prescriber/Patient relationship	~ 25 minutes	5/13/11
4	Fraudulent prescriptions and unusual patient behavior	~ 25 minutes	5/27/11
5	Filling and checking (including check out procedures)	~ 25 minutes	6/10/11
6	Audits, reporting and troubleshooting	~ 25 minutes	6/24/11

Sales Associates
will take
Modules 1, 4 and 5
Total time ~ 70 min.

Technicians
will take
Modules 1-5
Total time ~ 2 hrs.

Pharmacists &
Interns will take all
6 Modules
Total time ~ 2.5 hrs.

All modules dropped into the new GLMS on March 22nd.

Additional programs and mitigation strategies

Other

- Systems
 - Connexus enhancements will roll out to further enhance agreement
- Monitoring
 - Compliance monitoring will be on-going
 - CORT questions will focus on compliance with the agreement
- Credentialing
 - Enhanced background and professional credential checks
 - Random drug testing will begin where allowed by law

45

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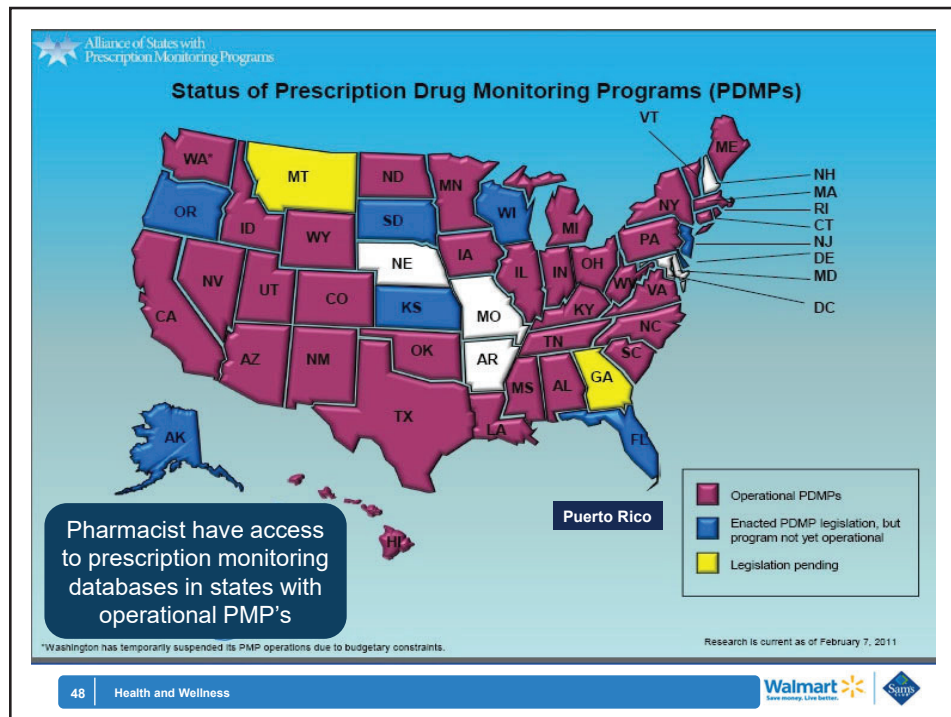
To ensure compliance with the obligations outlines in the Agreement, several other programs either are in place today, or will be released shortly.

From a systems perspective you will see Connexus enhancements.

Review of obligations and key concepts

Review of obligations

1. Ensure valid and accurate use of the prescriber's DEA number
(includes submission of data to state monitoring programs)
2. Ensure controlled substance prescription is valid and issued for a valid medical purpose
 - a) Monitor for valid prescriber-patient relationship, including out-of-state prescribers
 - b) Monitor for forged or altered prescriptions
 - c) Report all cases when the pharmacist determines that the prescription or relationship are not valid and therefore does not fill the prescription
3. Comply with state laws requiring ID check
4. Block early refill of controlled substance prescriptions
5. Other



This slide, from the Alliance for State Prescription Monitoring Programs shows active or pending PMP programs. If you are practicing on a state with an active program (purple), go to POM 1316 for details on how to enroll for access to the database if you haven't done so already.

5 States + PR

Review of key concepts

1. Ensure all information entered into Connexus is accurate
2. Ensure the security of the pharmacy and all controlled substances
3. Immediately report
 - a) Shortages or suspected diversion
 - b) Fraudulent or otherwise invalid prescriptions
 - c) Regulatory agency contact
 - d) Evidence of non-compliance
4. Use available resources
 - a) Prescription Monitoring Programs
 - b) Market Manager/Director
 - c) Regulatory Affairs
 - d) Asset Protection

Consequences of non-compliance

Consequences of Non-Compliance

- This MOA has been signed by Dr. Agwunobi and approved by senior leadership of Wal-Mart Stores, Inc.
- A violation may have serious consequences for Walmart, including a revocation of a pharmacy's DEA license.
- A single, inadvertent mistake that happens to violate the MOA will not subject Walmart to sanctions, but
- Any pattern of non-compliance, or any intentional violation, will be considered a violation of the MOA and will subject Walmart to serious consequences.

51

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Andy to provide



Paul Closing Comments

Thank you for your time and attention today. If you have any questions after viewing this presentation and reading the policies described here, please contact your Market Manager.



Welcome!

I would like to share some important information regarding an agreement between Wal-Mart Stores, Inc. and the Drug Enforcement Administration (DEA). I will be discussing details of the agreement and what has been done to implement this agreement.

Background - Administrative Memorandum of Agreement (MOA)

- Over the course of 15 months, Walmart and the DEA extensively negotiated an Administrative Memorandum of Agreement (MOA).
- The MOA applies to all Wal-Mart Stores, Inc. pharmacies, including Sam's Club and Puerto Rico.
- The MOA applies only to actions occurring after the effective date of the Agreement, March 17, 2011
- The term of the Agreement is four (4) years.
- Walmart will not pay any monetary fines or sanctions.

54

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- Over the course of 15 months, Walmart and the DEA extensively negotiated an Administrative Memorandum of Agreement (MOA).
- The MOA applies to all Wal-Mart Stores, Inc. pharmacies, including Sam's Club and Puerto Rico.
- The MOA applies only to actions occurring after the effective date of the Agreement, March 17, 2011
- The term of the Agreement is four (4) years.
- Walmart will not pay any monetary fines or sanctions.

Obligations, policy changes and expectations

55 | Health and Wellness



The agreement has several obligations, policy changes and expectations to be executed. Let's examine the Obligations

Obligations

1. Ensure valid and accurate use of the prescriber's DEA number
 - (includes submission of data to state monitoring programs)
2. Ensure controlled substance prescription is valid and issued for a valid medical purpose
 - a) Monitor for valid prescriber-patient relationship, including out-of-state prescribers
 - b) Monitor for forged or altered prescriptions
 - c) Report all cases when the pharmacist determines that the prescription or relationship are not valid and therefore does not fill the prescription
3. Comply with state laws requiring ID check
4. Block early refill of controlled substance prescriptions
5. Reporting, Training, CCTV recording

56

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In General – the obligations under the Agreement are as follows.

1. Ensure valid and accurate use of the prescriber's DEA number
(includes submission of data to state monitoring programs)

Change slide to show State Monitoring programs

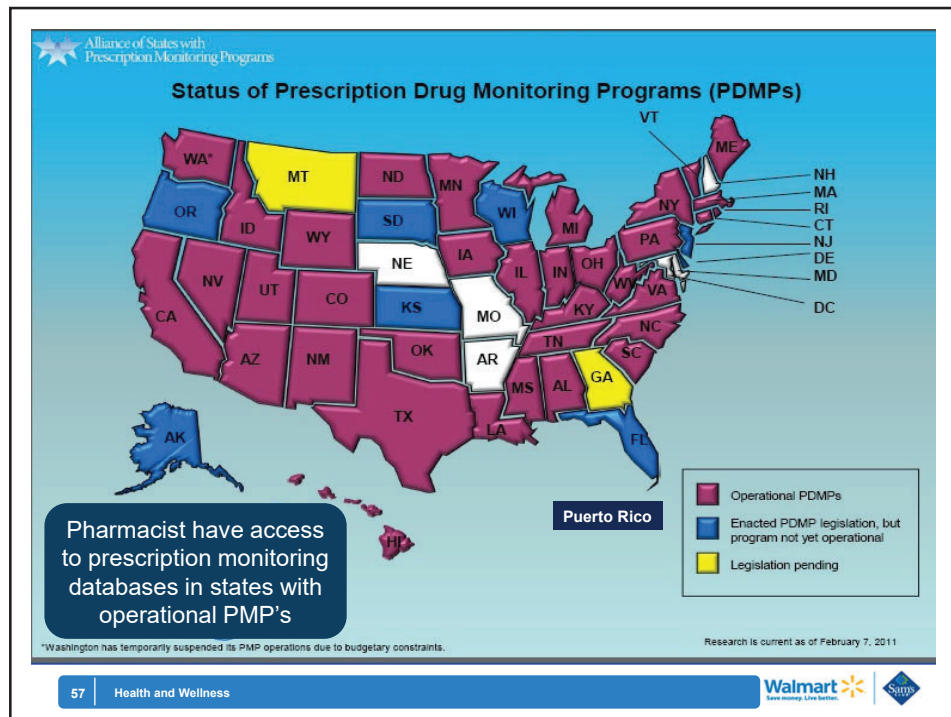
2. Ensure controlled substance prescription is valid and issued for a valid medical purpose
 - a) Monitor for valid prescriber-patient relationship, including out-of-state prescribers
 - b) Monitor for forged or altered prescriptions
 - c) Report all cases when the pharmacist determines that the prescription or relationship are not valid and therefore does not fill the prescription

3. Comply with state laws requiring ID check

4. Block early refill of controlled substance prescriptions

5. Reporting, Training, CCTV recording

Policy reviews were conducted and many Policies (POM's) were either updated or created to support of stores and clubs in being compliant with the MOA.



States in Purple already have a PMP program in place, Blue has passed legislation but not active yet and yellow states have Legislation pending. Arkansas pass legislation in March to create a PMP program which leaves only 4 states and PR to enact a program.

Obligations (continued)

1. Ensure valid and accurate use of the prescriber's DEA number
 - (includes submission of data to state monitoring programs)
2. Ensure controlled substance prescription is valid and issued for a valid medical purpose
 - a) Monitor for valid prescriber-patient relationship, including out-of-state prescribers
 - b) Monitor for forged or altered prescriptions
 - c) Report all cases when the pharmacist determines that the prescription or relationship are not valid and therefore does not fill the prescription
3. Comply with state laws requiring ID check
4. Block early refill of controlled substance prescriptions
5. Reporting, Training, CCTV recording

58

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2. Ensure controlled substance prescription is valid and issued for a valid medical purpose
 - a) Monitor for valid prescriber-patient relationship, including out-of-state prescribers
 - b) Monitor for forged or altered prescriptions
 - c) Report all cases when the pharmacist determines that the prescription or relationship are not valid and therefore does not fill the prescription
3. Comply with state laws requiring ID check
4. Block early refill of controlled substance prescriptions
5. Reporting, Training, CCTV recording

Policy reviews were conducted and many Policies (POM's) were either updated or created to support of stores and clubs in being compliant with the expectations and execution of our programs

Policy reference list

- Updated policies
 - POM 1311 – Valid Prescriber/Patient Relationship
 - POM 1315 – Monthly CII Audits
 - POM 1316 – Prescription Monitoring Programs
 - POM 1703 – Forged or Altered Prescriptions
- New policies
 - POM 1313 – Proper Identification
 - POM 1317 – Out-of-State Prescribers
 - POM 1318 – Early Refills
 - POM 1319 – Prescriber Identification

59

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Here is a recap of the eight policies that are impacted by this Agreement. These policies can be found on the WIRE

Updated policies

POM 1311 – Valid
Prescriber/Patient
Relationship

POM 1315 – Monthly CII
Audits

POM 1316 – Prescription

Monitoring Programs

POM 1703 – Forged or Altered Prescriptions

New policies

POM 1313 – Proper Identification

POM 1317 – Out-of-State Prescribers

POM 1318 – Early Refills

POM 1319 – Prescriber Identification

Policy reference list

- Additional policy resources
 - POM 807 – Receiving prescription orders
 - POM 901 – Asset Protection overview
 - POM 902 – Prescription area security
 - POM 903 – Filling Schedule II prescriptions
 - POM 911 – Diversion SOP
 - POM 913 – Post-diversion drug testing
 - POM 1304 – Pharmacy inspections

60

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There are additional policies related to controlled substances that are good reference for you as well.

Additional policy resources

POM 807 – Receiving
prescription orders

POM 901 – Asset Protection
overview

POM 902 – Prescription area

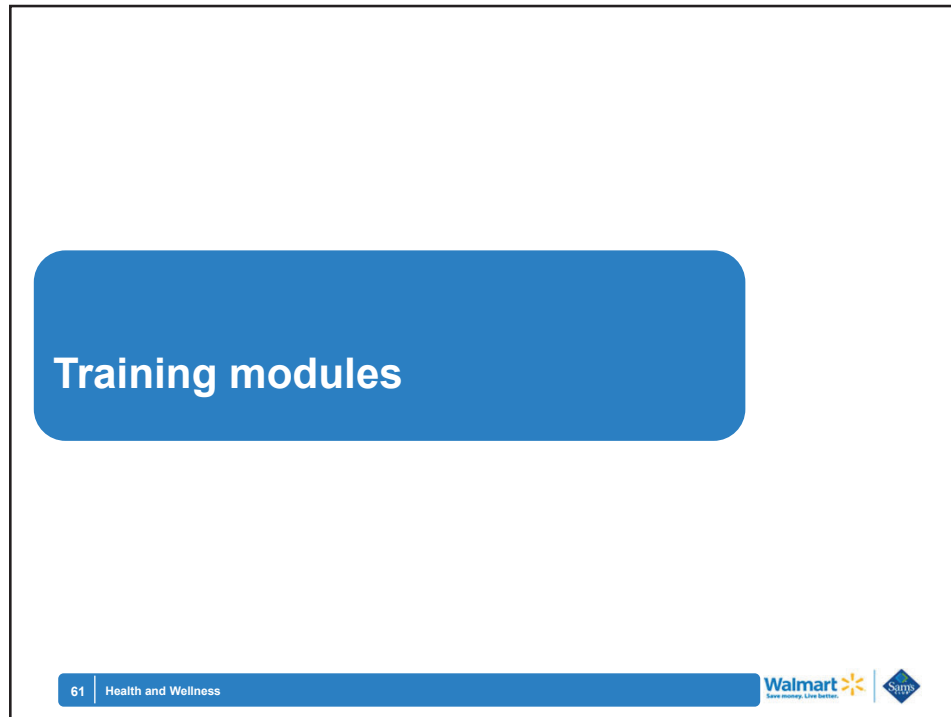
security

POM 903 – Filling Schedule II
prescriptions

POM 911 – Diversion SOP

POM 913 – Post-diversion drug
testing

POM 1304 – Pharmacy
inspections



Training Modules have been created to communicate the expectations for handling and dispensing Controlled substance prescriptions. There are 6 modules

Controlled substance training module schedule

Module	Topic	Seat time	Due date
1	Controlled substance security	~ 25 minutes	4/15/11
2	Dispensing procedures	~ 20 minutes	4/29/11
3	Prescriber/Patient relationship	~ 25 minutes	5/13/11
4	Fraudulent prescriptions and unusual patient behavior	~ 25 minutes	5/27/11
5	Filling and checking (including check out procedures)	~ 25 minutes	6/10/11
6	Audits, reporting and troubleshooting	~ 25 minutes	6/24/11

Sales Associates
will take
Modules 1, 4 and 5
Total time ~ 70 min.

Technicians
will take
Modules 1-5
Total time ~ 2 hrs.

Pharmacists &
Interns & Mgt will
take all 6 Modules
Total time ~ 2.5 hrs.

62 | Health and Wellness



All modules drop into the new GLMS on March 22nd.

1. Controlled substance security
2. Dispensing procedures
3. Prescriber/Patient relationship
4. Fraudulent prescriptions and unusual patient behavior
5. Filling and checking (including check out procedures)
6. Audits, reporting and troubleshooting

These modules are targeted at the job functions performed by the associates. Some associates will take 3 modules and others will take all 6 modules.

The associates are tested on their knowledge of the Controlled substance procedures at the end of each module.

Review of obligations and key concepts

Review of key concepts

1. Ensure all information entered into Connexus is accurate
2. Ensure the security of the pharmacy and all controlled substances
3. Immediately report
 - a) Shortages or suspected diversion
 - b) Fraudulent or otherwise invalid prescriptions
 - c) Regulatory agency contact
 - d) Evidence of non-compliance
4. Use available resources
 - a) Prescription Monitoring Programs
 - b) Market Manager/Director
 - c) Regulatory Affairs
 - d) Asset Protection

64

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Let's Recap

1. Ensure Information is entered in accurately into Connexus.
2. Ensure security of the Pharmacy and controlled substances
3. Immediately report the following occurrences
4. Resources - PMP, MD's MM's. Regulatory Affairs and AP

Other

- Systems
 - Connexus enhancements will roll out to further enhance agreement
- Monitoring
 - Compliance monitoring will be on-going
 - CORT questions will focus on compliance with the agreement
- Credentialing
 - Random drug testing will begin where allowed by law
 - Enhanced background and professional credential checks
- Training
 - Pharmacists, Interns, Technicians, Cashiers and Management

65

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To ensure compliance with the obligations outlined in the Agreement, several other programs either are in place today, or will be released shortly.

From a systems perspective you will see Connexus enhancements throughout the year

- Host Prescriber file updated weekly instead of monthly
- Prescriber address selection enhancements for Dr's with Multiple practice sites
- Multiple DEA numbers for Prescriber
- 4PT check screen will be enhanced to validate Prescriber information entered for the prescription
- Real time DEA number validation at input for Controlled substance prescriptions

Monitoring and follow-up

- Regional compliance directors
- Market Directors

- Regulatory Affairs

- Systems

Credentialing

- Random Drug screening to prevent diversion in state where allowed by law

- Background checks and Professional License verification

Training

- Existing Associates

- New hired Pharmacy Associates



As you can see the execution of this MOA required the entire H&W organization to work together

Senior Leadership

Regulatory Affairs

Legal

Operations

Compliance

Training and Development

Asset Protection

Policy review committee